

§ 35.10

10 CFR Ch. I (1–1–04 Edition)

for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements in this part under control number 3150–0010.

(b) The approved information collection requirements contained in this part appear in §§35.6, 35.12, 35.13, 35.14, 35.19, 35.24, 35.26, 35.27, 35.40, 35.41, 35.50, 35.51, 35.55, 35.60, 35.61, 35.63, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.190, 35.204, 35.290, 35.310, 35.315, 35.390, 35.392, 35.394, 35.404, 35.406, 35.410, 35.415, 35.432, 35.433, 35.490, 35.491, 35.590, 35.604, 35.605, 35.610, 35.615, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, 35.647, 35.652, 35.655, 35.690, 35.900, 35.910, 35.920, 35.930, 35.940, 35.950, 35.960, 35.961, 35.980, 35.981, 35.1000, 35.2024, 35.2026, 35.2040, 35.2041, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2204, 35.2310, 35.2404, 35.2406, 35.2432, 35.2433, 35.2605, 35.2610, 35.2630, 35.2632, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3047, and 35.3067.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In §35.12, NRC Form 313, including NRC Form 313A, which licensees may use to provide supplemental information, is approved under control number 3150–0120.

(2) [Reserved]

§ 35.10 Implementation.

(a) A licensee shall implement the provisions in this part on or before October 24, 2002, with the exception of the requirements listed in paragraph (b) of this section.

(b) A licensee shall implement the training requirements in §§35.50(a), 35.51(a), 35.55(a), 35.59, 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), and 35.690(a) on or before October 25, 2004.

(c) Prior to October 25, 2004, a licensee shall satisfy the training re-

quirements of this part for a Radiation Safety Officer, an authorized medical physicist, an authorized nuclear pharmacist, or an authorized user by complying with either:

(1) The appropriate training requirements in subpart J; or

(2) The appropriate training requirements in subpart B or subparts D through H.

(d) If a license condition exempted a licensee from a provision of Part 35 on October 24, 2002, then the license condition continues to exempt the licensee from the requirements in the corresponding provision of §§35.1–35.4002.

(e) When a requirement in this part differs from the requirement in an existing license condition, the requirement in this part shall govern.

(f) A licensee shall continue to comply with any license condition that requires it to implement procedures required by §§35.610, 35.642, 35.643, and 35.645 until there is a license amendment or renewal that modifies the license condition.

§ 35.11 License required.

(a) A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer byproduct material for medical use only in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraphs (b)(1) or (b)(2) of this section.

(b) A specific license is not needed for an individual who—

(1) Receives, possesses, uses, or transfers byproduct material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in §35.27, unless prohibited by license condition; or

(2) Prepares unsealed byproduct material for medical use in accordance with the regulations in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in §35.27, unless prohibited by license condition.

§ 35.12 Application for license, amendment, or renewal.

(a) An application must be signed by the applicant's or licensee's management.

(b) An application for a license for medical use of byproduct material as described in §§ 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000 must be made by—

(1) Filing an original and one copy of NRC Form 313, "Application for Material License," that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, authorized user(s), authorized medical physicist(s), and authorized nuclear pharmacist(s); and

(2) Submitting procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

(c) A request for a license amendment or renewal must be made by—

(1) Submitting an original and one copy of either—

(i) NRC Form 313, "Application for Material License"; or

(ii) A letter requesting the amendment or renewal; and

(2) Submitting procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

(d) In addition to the requirements in paragraphs (b) and (c) of this section, an application for a license or amendment for medical use of byproduct material as described in § 35.1000 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of this part.

(1) The applicant shall also provide specific information on—

(i) Radiation safety precautions and instructions;

(ii) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(iii) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

(2) The applicant or licensee shall also provide any other information requested by the Commission in its review of the application.

(e) An applicant that satisfies the requirements specified in § 35.13 of this chapter may apply for a Type A specific license of broad scope.

§ 35.13 License amendments.

A licensee shall apply for and must receive a license amendment—

(a) Before it receives, prepares, or uses byproduct material for a type of use that is permitted under this part, but that is not authorized on the licensee's current license issued under this part;

(b) Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except—

(1) For an authorized user, an individual who meets the requirements in §§ 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), 35.690(a), 35.910(a), 35.920(a), 35.930(a), 35.940(a), 35.950(a), or 35.960(a) and 35.59;

(2) For an authorized nuclear pharmacist, an individual who meets the requirements in §§ 35.55(a) or 35.980(a) and 35.59;

(3) For an authorized medical physicist, an individual who meets the requirements in §§ 35.51(a) or 35.961(a) or (b) and 35.59;

(4) An individual who is identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist—

(i) On a Commission or Agreement State license or other equivalent permit or license recognized by NRC that authorizes the use of byproduct material in medical use or in the practice of nuclear pharmacy;

(ii) On a permit issued by a Commission or Agreement State specific license of broad scope that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy;

(iii) On a permit issued by a Commission master material licensee that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy; or

(iv) By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

(c) Before it changes Radiation Safety Officers, except as provided in § 35.24(c);

(d) Before it receives byproduct material in excess of the amount or in a different form, or receives a different